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MAR 26 2002

Mr. James A. Grant  
Regulatory Compliance Officer  
Gaia Herbs  
108 Island Ford Road  
Brevard, North Carolina 28712

Dear Mr. Grant:

This is in response to your letter of December 19, 2001 to the Food and Drug Administration (FDA) pursuant to 21 U.S.C. 343(r)(6) (section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act (the Act)). In your letter, you notified us about a claim you intend to use for your dietary supplement **Cholesterol Vital Balance**.

The product **Cholesterol Vital Balance** uses the claim "Supports healthy cholesterol metabolism." In the preamble to the January 6, 2000 final rule on structure/function claims (see 65 FR 1000 at 1018), FDA stated that claims about the maintenance of normal cholesterol levels did not necessarily constitute implied disease claims. We stated, however, that because "many people think of cholesterol solely in terms of the negative role of elevated cholesterol in heart disease," in order to avoid implying that the product prevents or treats heart disease, a cholesterol maintenance claim would have to clarify that the product is only for maintenance of cholesterol levels that are already within the normal range. The claim for your product, including the name of the product which implies that the product is to effect blood cholesterol levels, contains no such clarification, however. Therefore, FDA considers it to be an implied claim to prevent coronary heart disease by preventing the development of elevated cholesterol levels or reducing elevated cholesterol.

21 U.S.C. 343(r)(6) makes clear that a statement included in labeling under the authority of that section may not claim to diagnose, mitigate, treat, cure, or prevent a specific disease or class of diseases. The statement that you are making for this product suggests that it is intended to treat, prevent, or mitigate a disease. This claim does not meet the requirements of 21 U.S.C. 343(r)(6). This claim suggests that this product is intended for use as a drug within the meaning of 21 U.S.C. 321(g)(1)(B), and that it is subject to regulation under the drug provisions of the Act. If you intend to make claims of this nature, you should contact FDA's Center for Drug Evaluation and Research (CDER), Office of Compliance, HFD-310, 7520 Standish Place, Rockville, Maryland 20855.

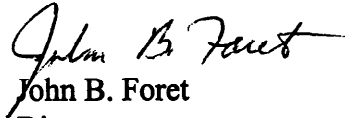
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Page 2 - Mr. James A. Grant

Please contact us if we may be of further assistance.

Sincerely,

A handwritten signature in cursive script, appearing to read "John B. Foret".

John B. Foret

Director

Division of Compliance and Enforcement

Office of Nutritional Products, Labeling

and Dietary Supplements

Center for Food Safety

and Applied Nutrition

**Copies:**

FDA, Center for Drug Evaluation and Research, Office of Compliance, HFD-300

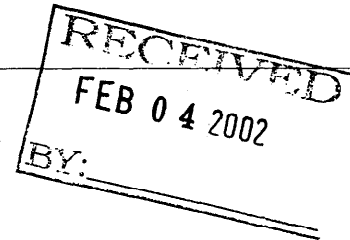
FDA, Office of the Associate Commissioner for Regulatory Affairs, Office of  
Enforcement, HFC-200

FDA, Atlanta District Office, Office of Compliance, HFR-SE140

# GAIA HERBS

*Manufacturers of Fresh Botanical Extracts*

Division of Compliance and Enforcement/ONPLDS  
Center for Food Safety and Applied Nutrition  
Food and Drug Administration  
HFS-810  
200 C Street, SW  
Washington, DC 20204



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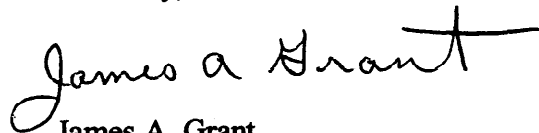
December 19, 2001

Dear Sir:

This letter is to provide notification, within the prescribed 30 days of marketing, of three new products that Gaia Herbs is adding to our line that contain structure function claims. These products are Liquid Phyto-Caps that are herbal dietary supplements. I have attached a copy of each label that contains the structure function claim as well as other information.

Please call at 828-883-5938 if you need addition information or if you have any questions.

Sincerely,



James A. Grant  
Regulatory Compliance Officer

#### SUGGESTED USE:

Take 1 capsule with a small amount of warm water 3 times daily between meals. Not to be used during pregnancy or lactation. Keep away from children. Use only as directed on label. Safety sealed for your protection. Keep bottle capped at all times and store in a cool dry place. Natural separation may occur. This does not affect product quality. If nausea occurs, please discontinue use temporarily.

**LIQUID PHYTO-CAPS™** - Gaia Herbs' patented technology delivers a concentrated full spectrum alcohol-free liquid extract in a 100% vegetarian capsule. Now you can have the superior bioavailability and fast absorption of a liquid delivery system, from certified organic and ecologically wildcrafted herbs, in a convenient capsule.

**ECOLOGICALLY WILDCRAFTED CERTIFIED ORGANIC**

\*THIS STATEMENT HAS NOT BEEN EVALUATED BY THE FOOD AND DRUG ADMINISTRATION. THIS PRODUCT IS NOT INTENDED TO DIAGNOSE, TREAT, CURE OR PREVENT ANY DISEASE.



EXTRA STRENGTH

## GAIA HERBS Liquid Phyto-Caps

# NICOTINE RELIEF

Promotes Protection from Environmental Stress\*

100% VEGETARIAN  
60 LIQUID-FILLED CAPSULES

A DIETARY SUPPLEMENT

#### Supplement Facts

Serving Size 1 Capsule	
Servings Per Container 60	
Amount Per 3 Capsules	mg
Calories 21	
ALCOHOL FREE CONCENTRATED EXTRACTS OF:	
Licorice Root ( <i>Glycyrrhiza uralensis</i> & <i>G. glabra</i> ) ♦	315 mg†
Lobelia Herb & Seed ( <i>Lobelia inflata</i> ) ▲	48 mg†
Wild Oats Milky Seed ( <i>Avena sativa</i> ) ▲	38.4 mg†
St. John's Wort ( <i>Hypericum perforatum</i> ) ●	36 mg†
Calamus Root ( <i>Acorus calamus</i> ) ●	30.3 mg†
Passionflower ( <i>Passiflora incarnata</i> ) ▲	26.4 mg†

†Daily Value not established.

Other ingredients: Vegetable glycerin, vegetable cellulose (capsule).

▲ = Ecologically Wildcrafted ♦ = Untreated Chinese Origin  
● = Certified Organic or Organically Cultivated

Each 2 capsules contain 5,250 mg crude herb equivalent.  
Gaia Herbs Liquid Phyto-Caps™ U.S. Patent No. 6,238,696 B1

Lot #  
Best by

Gaia Herbs, Inc., 108 Island Ford Rd., Brevard, NC 28712  
www.gaiaherbs.com

#### SUGGESTED USE:

Take 2 capsules with a small amount of warm water 2 times daily between meals. Not to be used during pregnancy or lactation. Keep away from children. Use only as directed on label. Safety sealed for your protection. Keep bottle capped at all times and store in a cool dry place. Natural separation may occur. This does not affect product quality.

**LIQUID PHYTO-CAPS™** - Gaia Herbs' patented technology delivers a concentrated full spectrum alcohol-free liquid extract in a 100% vegetarian capsule. Now you can have the superior bioavailability and fast absorption of a liquid delivery system, from certified organic and ecologically wildcrafted herbs, in a convenient capsule.

**ECOLOGICALLY WILDCRAFTED CERTIFIED ORGANIC**

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EXTRA STRENGTH

## GAIA HERBS Liquid Phyto-Caps

# HEALTHY SKIN & NAILS

with Gotu Kola and Silica

Supports Radiant & Vital Skin & Nails\*

100% VEGETARIAN  
60 LIQUID-FILLED CAPSULES

A DIETARY SUPPLEMENT

#### Supplement Facts

Serving Size 1 Capsule	
Servings Per Container 60	
Amount Per 2 Capsules	mg
Calories 14	
ALCOHOL FREE CONCENTRATED EXTRACTS OF:	
Triphala Powder Extract Blend containing w/ ( <i>Emblica officinalis</i> , <i>Terminalia bellerica</i> , <i>Terminalia chebula</i> ) ♦	200 mg†
Horseshoe ariel parts ( <i>Equisetum arvense</i> ) ▲	150 mg†
Alfalfa ariel parts ( <i>Medicago sativa</i> ) ▲	60 mg†
Gotu Kola Lf & Rt ( <i>Clematis asiatica</i> ) ▲	42 mg†
Yellow Dock Root ( <i>Rumex crispus</i> ) ▲	26 mg†
Nettle Leaf ( <i>Acorus calamus</i> ) ▲	22 mg†
Burdock Root ( <i>Arctium lappa</i> ) ▲	17 mg†
Figwort ariel parts ( <i>Scrophularia nodosa</i> ) ▲	6 mg†
Oregon Grape Root ( <i>Berberis aquifolium</i> ) ●	5 mg†
Asiaticanthen	4 mg†

Horseshoe, Nettle & Alfalfa Mineral Ash

STANDARDIZED TO FULL SPECTRUM ACTIVITY PROFILE

Bioactivity Per 2 Capsules	mg Activity
Silica from Horseshoe	60 mg†
Total triterpenoids from Gotu Kola	3.2 mg†

†Daily Value not established.

Other ingredients: Vegetable glycerin, vegetable cellulose (capsule).

▲ = Certified Organic or Organically Cultivated ♦ = Untreated Ayurvedic Origin  
● = Ecologically Wildcrafted

Each 2 capsules contain 3,000 mg crude herb equivalent.  
Gaia Herbs Liquid Phyto-Caps™ U.S. Patent No. 6,238,696 B1

Lot #  
Best by

Gaia Herbs, Inc., 108 Island Ford Rd., Brevard, NC 28712  
www.gaiaherbs.com

#### SUGGESTED USE:

Take 2 capsules with a small amount of warm water 2 times daily between meals. Not to be used during pregnancy or lactation. Keep away from children. Use only as directed on label. Safety sealed for your protection. Keep bottle capped at all times and store in a cool dry place. Natural separation may occur. This does not affect product quality.

**LIQUID PHYTO-CAPS™** - Gaia Herbs' patented technology delivers a concentrated full spectrum alcohol-free liquid extract in a 100% vegetarian capsule. Now you can have the superior bioavailability and fast absorption of a liquid delivery system, from certified organic and ecologically wildcrafted herbs, in a convenient capsule.

**ECOLOGICALLY WILDCRAFTED**

\*THIS STATEMENT HAS NOT BEEN EVALUATED BY THE FOOD AND DRUG ADMINISTRATION. THIS PRODUCT IS NOT INTENDED TO DIAGNOSE, TREAT, CURE OR PREVENT ANY DISEASE.



EXTRA STRENGTH

## GAIA HERBS Liquid Phyto-Caps

# CHOLESTEROL VITAL BALANCE

Supports Healthy Cholesterol Metabolism\*

100% VEGETARIAN  
60 LIQUID-FILLED CAPSULES

A DIETARY SUPPLEMENT

#### Supplement Facts

Serving Size 1 Capsule	
Servings Per Container 60	
Amount Per 2 Capsules	mg
Calories 14	
ALCOHOL FREE CONCENTRATED EXTRACTS OF:	
Panthenol	200 mg†
Artichoke leaf ( <i>Cynara scolymus</i> ) ▲	200 mg†
Coleus root ( <i>Coleus forskohlii</i> ) ●	180 mg†
Guggulu resin ( <i>Commiphora mukul</i> ) ●	150 mg†
Wild Yam rhizome ( <i>Dioscorea villosa</i> ) ●	22 mg†
Policosanol	10 mg†
Meadow rhizome ( <i>Podophyllum peltatum</i> ) ●	8 mg†

†Daily Value not established.

Other ingredients: Vegetable glycerin, vegetable cellulose (capsule).

▲ = Certified Organic or Organically Cultivated

● = Ecologically Wildcrafted

Each 2 capsules contain 3,600 mg crude herb equivalent.  
Gaia Herbs Liquid Phyto-Caps™ U.S. Patent No. 6,238,696 B1

Lot #  
Best by

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www.gaiaherbs.com